ISRCTN70419473 https://doi.org/10.1186/ISRCTN70419473

Early Positive Approaches to Support (E-PAtS) feasibility study

Submission date
27/02/2018

Recruitment status
No longer recruiting

Registration date
14/03/2018

Overall study status
Completed

Last Edited
10/01/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Children with intellectual disability (ID) have a low level of intellectual ability and usually need help with everyday tasks (e.g., self-care, communication). Children with ID also are more likely to have challenging behaviour and parents are more likely to experience additional stress than parents of children without ID. A parenting programme has been developed for parents of young children (aged 1½ to 5 years) with ID called Early Positive Approaches to Support (E-PAtS). In E-PAtS, parents are taught in a group to learn practical strategies over 8 weeks that help them to look after themselves, and help them with their child's development. A parent of a child with ID and a parenting professional co-deliver E-PAtS, after they receive training themselves. The aim of this study is to assess the feasibility of delivering E-PAtS successfully to parents/caregivers of children with ID by community parenting support provider organisations. If the study works well a much larger study can be planned in future.

Who can participate?
Families with at least one child with an ID aged 18 months to 5 years

What does the study involve?
Participating families are randomly allocated to either attend E-PAtS group sessions, which run for 8 weeks (2.5 hours a week), or to only receive usual care (with the option to attend E-PAtS 12 months later). All families also continue to receive usual practice in their local area. Mothers, fathers and other adult caregivers in the home are invited to take part. All parents, whether they attend the E-PAtS groups or not, are asked questions about what may have changed for them during E-PAtS. The most important questions are changes in parents' psychological well-being. Other measures include: the parents' mental health, positive perceptions, approaches to parenting, relationships with their partner (if they have one) and child with ID, the positive and problem behaviour of a brother or sister, sibling relationships, and how much the families access a variety of different services (especially social care, health services). The study also assesses whether parents are willing to take part in the research, if they attend most of the E-PAtS course, whether they complete the research measures, and whether organisations who deliver parenting courses would be interested in taking part in a larger study. After the E-PAtS courses have been run, mothers and fathers, the people who deliver E-PAtS, and people from the organisations providing E-PAtS are also interviewed about what encouraged them to take part in

the research, what got in the way of this, and their positive and difficult experiences in the E-PAtS groups.

What are the possible benefits and risks of participating?
Because E-PAtS is a new programme, it is not yet known whether it will benefit parents but by taking part in this study participants will be helping the researchers answer whether the E-PAtS group sessions are beneficial to parents of children with learning disability. The results of this study may benefit parents of children with learning disability in the future. If participants take part in this study they may or may not be selected to attend an E-PATS group straightaway. Whether or not participants take part in an E-PAtS group, they will be asked to spare some time to fill out questionnaires. The questionnaires and E-PAtS group sessions include positive things, but will also ask participants to reflect on challenges they may face with their child. However, it is not thought that taking part in the study will pose any risk to parents or their children.

Where is the study run from?
1. University of Warwick (UK)
2. University of Kent (UK)

When is the study starting and how long is it expected to run for?
January 2018 to October 2019

Who is funding the study?
NIHR Public Health Research Programme (UK)

Who is the main contact?
Dr Elinor Coulman

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHR 15/126/11

Study information

Scientific Title
Early Positive Approaches to Support (E-PAtS) for families of young children with intellectual disability: a feasibility study

Study objectives
To assess the feasibility of delivering E-PAtS successfully to parents/caregivers of children (18 months-5 years) with ID by community parenting support provider organisations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Humanities and Social Sciences Research Ethics Committee, University of Warwick, 14/12/2017, ref: 30/17-18

Study design
Feasibility study of an interventional cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant infromation sheet

Health condition(s) or problem(s) studied
Support for families (parents/carers) of children with intellectual disability

Interventions
Families will be randomised using an allocation 1:1 ratio to E-PAtS or Usual Practice (UP). Randomisation will occur using randomly permuted blocks and will be developed by the study statistician. Intervention participants will be allocated to attend the E-PAtS group sessions, which will run for 8 weeks (2.5 hours a week), and control will be allocated to usual care. If they are assigned to receive usual support, families will be given the option of receiving E-PAtS 12 months after recruitment. All families will also continue to receive usual practice in their local

area. Mothers, fathers or other adult caregivers in the home will be invited to take part. All parents, whether they attend the E-PAtS groups or not, will be asked to answer questions about what may have changed for them during E-PAtS. The most important questions will be changes in parents' psychological well-being. Other measures include: the parents' mental health, positive perceptions, approaches to parenting, relationships with their partner (if they have one) and child with ID, the positive and problem behaviour of a brother or sister, sibling relationships, and how much the families access a variety of different services (especially social care, health services). The study will find out if parents are willing to take part in the research, if they attend most of the E-PAtS course, whether they complete the research measures, and whether organisations who deliver parenting courses would be interested in taking part in a larger study. After the E-PAtS courses have been run, the trialists will also interview mothers and fathers, the people who deliver E-PAtS, and people from the organisations providing E-PAtS. They will be asked about what encouraged them to take part in the research, and what got in the way of this. They will also be asked about their positive and difficult experiences in the E-PAtS groups.

Intervention Type
Behavioural

Primary outcome measure
Measured at baseline, 3 months post-randomisation and 12 months post-randomisation. The method of data collection will be dependent on the preference of the participant at the screening/recruitment interview. Data will therefore be collected face-to-face, over the telephone or by post. All data collection forms will be paper CRFs/questionnaires
1. The feasibility of recruiting eligible participants to the study and the most effective recruitment pathways to identify families of young children with ID
2. The feasibility of recruiting suitable providers and facilitators to run E-PAtS parenting groups
3. Recruitment rates, adherence to the intervention and retention rates
4. The views of providers and facilitators regarding delivering the intervention and study processes
5. The views of parents/caregivers regarding the intervention and study processes
6. The views of parents/caregivers regarding randomisation within the context of a RCT
7. Fidelity of implementation of the E-PAtS intervention through observation and participant /facilitator interviews
8. Usual practice in this setting and use of services/support in both groups
9. The feasibility of the outcome measures and whether there is preliminary evidence of differences on these measures between the intervention and control group
10. The feasibility of collecting resource use and health related quality of life data for parents and the child with ID to conduct health economic evaluation
11. The views of parents/caregivers regarding the acceptability of using their routinely collected data within the context of a RCT

Secondary outcome measures
A range of established outcome measures, proposed to test the intervention in a main trial, will be measured. All outcome measures will be assessed on paper CRFs over the telephone, face to face or by post (participant preference) at baseline, 3 months post randomisation and 12 months post randomisation, with the exception of VABS which will only be measured at baseline and 12 months post randomisation. The outcome measures include:
1. Parent impact secondary outcomes (measures for both parents, irrespective of whether they attended the E-PAtS intervention):
2.1. Parental psychological well-being, measured using the Warwick-Edinburgh Mental Well-Being Scale

2.2. Parental anxiety and depression, measured using the Hospital Anxiety and Depression scale
2.3. Parent health-related quality of life, measured using EQ-5D-5L
2.4. Parental situational coping approaches (i.e., coping strategies related to the care of their child with ID), measured using the Brief COPE
2. Secondary outcomes – child with ID:
2.1. Behavioural and emotional problems, and language development, measured using the Child Behavior Checklist (CBCL) for children 1.5-5 years of age including the language development survey supplement
2.2. Adaptive skills and behaviour problems of the child with ID measured with the Vineland Adaptive Behaviour Scales (VABS – 3rd edition). The VABS has an overall standardised Adaptive Composite, and a further three standardised scores for key domains measured across the age range for this study: communication, socialisation, and daily living skills. Parents will also report on "maladaptive" behaviours in the VABS
2.3. Child health-related quality of life, measured using the Paediatric Quality of Life InventoryTM Version 4.0 Generic Core Scales
3. Secondary outcomes – family and family systems:
3.1. Parent relationship with partner (if relevant), measured with the Happiness of relationship scale
3.2. Perception of family functioning/quality of life, measured with the Family APGAR scale
3.3. Sibling behavioural and emotional problems where there is at least one sibling in the family between the ages of two and 16 years of age, measured with SDQ
3.4. Sibling relationship quality, measured with the Sibling Relationship Questionnaire (revised) (where relevant)
3.5. Social support available to the family, measured with the Family Support Scale
3.6. Criticism and warmth in the parent-child relationship from parents' perspectives, coded independently from the Five Minute Speech Sample
4. Secondary outcomes assessing primary mechanisms of impact:
4.1. Parenting efficacy, measured with 7 items from the Parenting Sense of Competence Scale
4.2. Parental perceptions of the positive impact of their child, measured with the Positive Gains Scale
4.3. Relationship with partner and co-parenting (if relevant) - disagreement over issues related to child, co-parenting
4.4. Parenting relationship and other family interactions, measured with child-parent relationship scale, and a parent activities/involvement index
4.5. (For parents in families randomised to E-PAtS) Group members' perceived support from the group evaluation, measured with 8 items from the Group Cohesion Scale

Overall study start date
01/01/2018

Completion date
30/04/2020

Eligibility

Key inclusion criteria
1. Family units with at least one child with an ID aged 18 months-5 years
2. The identified child with ID meets the following:
2.1. An administrative label of ID (learning disability/learning difficulties in UK terminology) AND
2.2. Has a standard score on the Vineland Adaptive Behaviour Scales composite score of <80

3. At least one parent/caregiver is available to attend the E-PAtS intervention
4. Parent/caregivers who are to participate in the study are ≥ 18 years old
5. Parent/caregivers who are to participate in the study have a level of English language enabling (verbal) completion of outcome measures

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
128

Total final enrolment
74

Key exclusion criteria
1. The identified child with ID is in a 24-h residential placement
2. The identified child with ID is in a foster placement due to end before the 12-month post-randomisation follow up data collection point
3. The primary caregiver is enrolled at baseline in a group or individually-delivered parenting programme outside of the study
4. The primary caregiver is enrolled in a programme of personal psychological therapeutic support at baseline
5. Any parent in the family has already participated in an E-PAtS group
6. There are current child protection concerns relating to the identified child with ID that have been identified by professionals/services and indicated to programme facilitators or their host organisation at the point of recruitment
7. The family are recognised to be in a state of current crisis/a score of 8+ on the 10-point Brief Family Distress Scale

Date of first enrolment
01/04/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Warwick
Warwick
United Kingdom
CV4 7AL

Study participating centre
University of Kent
Canterbury
United Kingdom
CT2 7LR

Sponsor information

Organisation
University of Warwick

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Sponsor type
University/education

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists plan to publish the protocol as soon as possible. Outputs from the E-PAtS Feasibility Study will include open access peer reviewed journal articles in international academic journals, at national and international academic conferences and at University public engagement events. All publications and presentations relating to the study will be authorised by the SMG.

Intention to publish date
30/04/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/10/2020	08/10/2020	Yes	No
Results article		21/12/2021	10/01/2022	Yes	No